90-1281

No.

Supreme Court, U.S.
FILED
FEB 7 1991
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In The

Supreme Court of the United States

October Term, 1990

BARRY GLEICHER and BIOPHARMACEUTICS, INC., formerly PATIENT MEDICAL SYSTEMS CORP.,

Petitioners,

vs.

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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QUESTIONS PRESENTED FOR REVIEW

1. Is it a violation of Petitioners' due process rights requiring reversal of a criminal conviction for fraud when: (a) the sole basis of the fraud charged is failure to comply with interpretive regulations, which were not promulgated under the Administrative Procedure Act and are not entitled to the force and effect of law; (b) the Government's position completely contradicts its position in other litigation in which it argued that these interpretive regulations have no force and effect of law; (c) the interpretive regulations cited by the Government do not apply to Petitioners and do not support the "rules" it charged Petitioners with violating; and (d) the very "rules" articulated by the Government rely on a term that has more than one meaning?

2. Does the Public Protection Clause of the Paperwork Reduction Act, 44 U.S.C. § 3512, require reversal of a criminal conviction for fraud where the fraud alleged is only the failure to comply with information collection requests that never received Office of Management and Budget approval?

3. Does the Second Circuit's holding that a Magistrate's jurisdiction to select a jury does not require a written waiver by the defendant in a criminal case, create a conflict with the Ninth Circuit, which held in *United States v. France,* 88 F.2d 223 (9th Cir. 1989), *aff'd by equally divided court,* 59 L.W. 4089 (Jan. 22, 1991) (Justice Souter did not participate), that *United States v. Gomez,* 109 S.Ct. 2237 (1989) required such a waiver?

4. In light of this Court's grant of certiorari in *Pertz v. United States,* 59 L.W. 3377 (Jan. 22, 1991), should this case, which contains virtually the exact same facts be joined therewith, or held pending decision?

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PRELIMINARY STATEMENT

Petitioners, BARRY GLEICHER and BIOPHARMACEUTICS, INC., formerly PATIENT MEDICAL SYSTEMS CORP. ("PMS")[1], respectfully request that a writ of certiorari

1. Biopharmaceutics, Inc., a publicly-owned Delaware corporation, has no parent corporation or subsidiaries except a wholly-owned subsidiary, (Cont'd)

be granted to review a Judgment and Opinion of the United States Court of Appeals for the Second Circuit entered in the above-captioned proceeding.

OPINION BELOW

The United States District Court for the Eastern District of New York (Wexler, J.), wrote no opinion. The Decision of the United States Court of Appeals for the Second Circuit affirming the convictions is reported at 914 F.2d 1514 (2d Cir. 1990), and is reprinted in the Appendix herewith.[2] The Second Circuit further denied Petitioners' Petitions for Rehearing on November 9, 1990 and November 22, 1990, and a copy of these Orders are contained in the Appendix herewith.

JURISDICTION AND TIMELINESS

The jurisdiction of this Court is invoked under Title 28, United States Code, § 1254(1). This Petition is timely because it was filed within ninety days of the Second Circuit's denial of the Petitioners' timely Petitions for Rehearing on November 9 and November 22, 1990.

(Cont'd)
Biopharmaceutics, Inc., a New York corporation, 100 percent of the stock of which was purchased, subsequent to the events at issue in the Indictment, by Patient Medical Systems Corp., a defendant below. The only affiliate corporation is Outback Oil & Mineral Exploration Corporation, a publicly-owned corporation which is a major shareholder in Biopharmaceutics, Inc. Defendant Patient Medical Systems Corp. changed its name in 1987 to Integrated Generics, Inc., consistent with its changing its line of business to generic drugs. In 1988, Integrated Generics, Inc., was reincorporated in Delaware as Biopharmaceutics, Inc.

2. All references to the Appendix shall be listed as "___a."

PROVISIONS INVOLVED

The provisions involved include the following statutes, regulations and provisions of the Medicare Carriers Manual, the relevant text of which is set forth in Appendix at 127a.

I. STATUTES

Administrative Procedure Act

5 U.S.C. § 553 — Rule Making

Paperwork Reduction Act

44 U.S.C. § 3507 — Public information collection activities — Submission to Director; approval and delegation

44 U.S.C. § 3512 — Public protection

Magistrate's Act

28 U.S.C. § 636 — Jurisdiction, powers and temporary assignment

Criminal Code

18 U.S.C. § 3401 — Misdemeanors; application of probation laws

II. REGULATIONS

Office of Management and Budget

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III. *Medicare Carriers Manual Provisions*

§ 3102.B AREA CARRIER — SUPPLIER'S SERVICES — *Suppliers with Branch Offices or Sales/Rental Outlets in More Than One Carrier Jurisdiction*

§ 3110. TRANSFERRING REQUESTS FOR MEDICARE PAYMENT

§ 4011.8 *Item 8: Name and Address of Physician or Supplier*

§ 4105.5 *Claims From Suppliers With Central Billing Operations For Branch Offices in More Than One Carrier's Jurisdiction*

§ 4105.8 *Claims From Suppliers With Central Billing Operations For Branch Offices in More Than One Carrier's Jurisdiction*

STATEMENT OF CASE

Petitioner PMS was a Medicare supplier that provided durable medical equipment and disposable medical supplies to Medicare Part B beneficiaries[3] in various states. Petitioner, BARRY

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3. The Medicare Program, administered by the Department of Health and Human Services ("HHS") through HCFA, is a system of health insurance for the elderly and the disabled. See Social Security Amendments of 1965, Public Law 89-97, Title I, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. § 1395, et seq.) ("Medicare Act"). Medicare Part B benefits cover the purchase and rental of durable medical equipment, such as seat-lift chairs. 42 U.S.C. § 1395l; 42 C.F.R. § 410.10(h), 410.38 (1988). In purchasing or renting such equipment, a beneficiary may assign his entitlement to Part B benefits to the supplier. The (Cont'd)

GLEICHER ("Gleicher") was a Vice-President of PMS.[4]

PMS provided supplies and equipment, ranging from enteral feeding supplies to seat-lift chairs, to Medicare beneficiaries and accepted an asignment of the beneficiaries' claims as payment. PMS submitted these claims to private insurance companies that had contracted with the Health Care Financing Administration ("HCFA"), to serve as Medicare carriers.[5] Each claim was submitted on "form HCFA-1500" ("the claim form") (56a) the form prescribed by HCFA. PMS utilized the same procedures for filing claims as did other multi-state suppliers: claims from various states were processed through a central computer and submitted to the Medicare carriers through regional offices.

In the summer of 1985, some of these private carriers began to create their own billing instructions describing the "appropriate carrier" with which particular claims should be filed. Each carrier developed its own instructions, often conflicting with those of other carriers. Subsequently, each carrier, citing its version of

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(Cont'd)
supplier then submits the claim to the Medicare carrier and payment is made directly by the carrier. 42 U.S.C. § 1395f; 42 C.F.R. § 405.250 (1987).

4. Another Vice President for PMS, STEVEN B. WEISS ("Weiss"), and another corporation, HEALTH-MED, INC. ("Health-Med"), were also indicted, jointly tried and convicted with the Petitioners. At this time, Weiss' appeal is still pending before the Second Circuit. *United States v. Weiss*, No. 90-1086 (2d Cir.) Health-Med is out of business and elected not to appeal.

5. HCFA is responsible for operational direction and policy guidance in administration of the Medicare Act. 42 C.F.R. §§ 401.101, 401.108 (1989). Additionally, it is empowered to negotiate and administer agreements with individual Medicare carriers. 42 U.S.C. § 1395u; 42 C.F.R. § 421.200 (1989). The carriers are expected to review each claim, make a determination of "reasonable charge," and pay the claim. 42 U.S.C. § 1395u; 42 C.F.R. §§ 405.501, 405.502 (1989).

the instructions, denied that it was the "appropriate carrier" to process PMS' claims.[6] The claims were shifted from carrier to carrier or back to PMS, so that numerous claims were not processed or paid for over two years.[7] As a result, PMS was forced to leave the health care business.

In 1987, PMS initiated a civil action against the Secretary and a Medicare carrier to challenge the validity of these uncodified, ad hoc, inconsistent, and arbitrary billing instructions. *Integrated Generics, Inc. v. Bowen,* CV87-2032 (E.D.N.Y.) (stayed pending decision in *United States v. Weiss,* No. 90-1086 (2d Cir.)). In response, the Government initiated this action indicting PMS, Gleicher, Weiss and Health-Med for conspiring to defraud the United States, mail fraud, and making false statements on Medicare claim forms.

---

6. Different carriers were using different reasons to justify their refusal to process and pay PMS' Medicare claims. Carriers outside of New York state asserted that PMS' principal place of business was in Franklin Square, New York, and therefore all claims should be submitted to the carrier for that geographic jurisdiction, Empire Blue Cross/Blue Shield of New York. At the same time, however, Empire refused to pay the claims and asserted that they should be submitted to the carrier within the geographic jurisdiction in which the beneficiary resided. (75a-76a).

The New Jersey carrier advised co-defendant Steven B. Weiss, then President of Health-Med, which had an office in New Jersey, that the New Jersey carrier would only accept claims for New Jersey beneficiaries, and claims for New York beneficiaries should be submitted to a New York carrier (13a, 78a). Yet, this same carrier, at approximately the same time, advised Gleicher "since you are from New York, you should send any claims you have for New Jersey Medicare patients to your carrier in New York" (14a, 77a). This carrier was thus using the "beneficiary's address" basis to avoid claims from Health-Med, and the "office address" basis to avoid claims from Gleicher.

7. PMS is presently owed payment for numerous claims. The amount due far exceeds the amount of fine imposed by the court, and any claim for overpayment made by the government.

The Prosecution's entire case was premised on the argument that the Medicare Carrier's Manual ("CM") provisions created "point of sale rules", and that Petitioners fraudulently and falsely circumvented these "rules"[8]. The trial judge made clear that the existence of the rules was an essential premise to a finding of wrongdoing:

> If there are no rules and regulationss, there cannot be any fraud, it's that simple. I rule that there was [sic] regulations . . .

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8. The essence of the Prosecution's fraud and false statements theories is contained in the following paragraphs of the Indictment:

> 14. Pursuant to the HHS Medicare Carriers Manual, '(Manual)', which is provided to all Medicare suppliers, a carrier's jurisdiction to receive, analyze and pay Medicare claims, and the basis for the carrier's calculation of the amount of reimbursement to which suppliers are entitled, is determined, in part, by the location where the service is furnished to the beneficiary, i.e., the location where the supplier meets with the beneficiary or receives the beneficiary's call for the supplier's services. This location is known as the "point of sale".
>
> 15. A Medicare provider is eligible to receive only the prevailing rate of reimbursement in the geographic location of the point of sale. Pursuant to the Manual, Medicare suppliers are required to file Medicare claims with the Medicare carriers located in the geographic location where the services were furnished, i.e., the point of sale.
>
> 16. The Medicare Claim Form requires the supplier to list its name and address. The Manual requires that suppliers with branch offices located in more than one carrier's jurisdiction identify on the Claim Form the address of the branch office actually supplying the service to the Medicare beneficiary. . .

(37a-38a).

(85a). The Government specifically agreed.[9]

Jury selection for the criminal trial was conducted on April 3, 1989 before Federal Magistrate David F. Jordan. The Magistrate did not request, and the Petitioners did not provide, written waivers of their rights to have an Article III Judge preside at the jury selection.[10]

Petitioners were jointly tried and convicted. The Second Circuit affirmed the convictions of Gleicher and PMS on September 19, 1990 implicitly accepting the validity and enforceability of the "point of sale rules" in its decision (9a). Both Petitioners submitted timely Motions for Rehearing, and these motions were denied on November 9, 1990 and November 22, 1990, respectively.

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9. The trial judge provided this explanation in the civil trial, which was stayed until the conclusion of the criminal proceedings. At that time, the government attorney explained that if there were no rules or regulations that prohibited Petitioners' conduct, "then obviously the criminal indictment would have to have been thrown out." (83a).

10. The Prosecution submitted an affirmation in opposition to Petitioners' joint motion for a judgment of acquittal and asserted that counsel had orally consented to the Magistrate's supervision of jury selection. (124a).

REASONS FOR GRANTING THE WRIT

I.

THE CONVICTIONS ARE BASED ON VIOLATIONS OF PETITIONERS' DUE PROCESS RIGHTS AND MUST BE REVERSED.

A. The "Point of Sale Rules" Contained In The Carrier's Manual, Which Were Never Promulgated Under The Administrative Procedure Act, Are Unenforceable and Cannot Support The Convictions.

1. The Indictment and Prosecution Were Based On Violations Of The Point Of Sale Rules Contained In The Carrier's Manual.

Petitioners were charged with and convicted of mail fraud, 18 U.S.C. § 1341, conspiring to defraud the United States, 18 U.S.C. § 371, and making false statements on Medicare and Medicaid forms, 42 U.S.C. § 1395n(a)(1) and § 1396h(a)(1) (1982 ed.). Convictions for mail fraud and conspiring to defraud the United States must be reversed if the existence of a fraud is not proven. See *O'Malley v. New York City Transit Authority,* 896 F.2d 704, 706-07 (2d Cir. 1990) (mail fraud); *United States v. Weischenberg,* 604 F.2d 326, 331-32 (5th Cir. 1979) (conspiracy to defraud the United States). A conviction for false statements must be reversed if the statement is literally true. *See Bronston v. United States,* 409 U.S. 352, 362 (1973) (reversing conviction for perjury because statement was literally true, even though it was unresponsive and "false by negative implication").

Every count in the Indictment is based on the premise that petitioners were legally obligated to comply with certain "point

of sale rules" contained in the CM[11] and that Petitioners' failure to comply with these "rules" constituted fraud and made the statements by petitioners literally false (37a-38a, 70a-71a, 96a). These alleged "point of sale rules" relied on by the Prosecution were: (1) That Medicare suppliers are required to file claim forms with the "appropriate" Medicare carrier in the geographic location where the "point of sale" occurred, and (2) that multi-office Medicare suppliers are required to "place the address for the branch office covering the point of sale in box 31 of the claim form" (37a-38a, 96a-97a).

At trial, the Prosecution argued that, based on the "point of sale rules", a New York carrier was the "appropriate" carrier to process Petitioners' seat-lift chair claims, that Petitioners knew claims should have been submitted to a New York carrier and that Petitioners' New York office address, rather than its Ohio or Illinois office addresses should have been listed in box 31. Thus, the Prosecution argued, the Petitioners acted fraudulently by filing claim forms with "inappropriate" carriers and made false statements by placing the wrong branch office address in box 31.[12]

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11. The CM provisions relied on by the Prosecution are fully set forth in the Appendix and are discussed in more detail at page 19, *infra*. The term "point of sale" however, is never used in the CM.

12. The Prosecution argued that Petitioners' motivation for submitting claim forms to the Ohio carrier was to obtain a higher reimbursement rate. In fact, no such motivation on Petitioners' part can be inferred. The New York carrier, which according to the Prosecution was the "appropriate" carrier for certain claims, actually paid a *higher* rate of reimbursement than the Ohio carrier paid at that time. (65a). Assuming *arguendo*, however, that Petitioners were seeking a higher reimbursement in submitting these claims to the Ohio carrier, this in itself is *not* improper when there is no requirement that a Medicare supplier submits its claims to a particular carrier and there is no prohibition against seeking the highest reimbursement. *See United States v. Zacher*, 586 F.2d 912, 916 (2d Cir. 1978); *United States v. Porter*, 591 F.2d 1048, 1057 (5th Cir. 1979); *see also, Helvering v. Gregory*, 69 F.2d 809, 810 (2d Cir. 1934).

The Prosecution, the trial court[13] and the Second Circuit[14] all assumed that the "point of sale rules" imposed a legal obligation on Petitioners to file claims with a particular carrier and to complete box 31 of the claim form in a particular way. Yet, these "rules" can only give rise to such obligations if the CM is entitled to the force and effect of law. *See Schweiker v. Hansen,* 450 U.S. 785, 789 (1980) (per curia) (examining the Social Security Claims Manual and explaining that it "is not a regulation. It has no legal force. . ."); *United States v. Reinis,* 794 F.2d 506, 508 (9th Cir. 1986) (reversing fraud conviction because the currency transaction reporting "rule" relied on by Prosecution was never promulgated under the APA); *Glick v. Secretary of HHS,* 714 F. Supp. 39, 41 (D.C. Mass. 1989). If the CM provisions are not entitled to the force and effect of law, the convictions must be overturned. *United States v. Vail,* 252 F. Supp. 823, 825 (S.D. Ohio, 1966); *United States v. Zacher,* 586 F.2d 912, 916 (2d Cir. 1978); *United States v. Porter,* 591 F.2d 1048, 1057 (5th Cir. 1979); *United States v. Reinis, supra.*

2. Rules Not Promulgated Under The Administrative Procedure Act Are Merely Interpretive Regulations And Are Not Enforceable.

The Medicare Act provides *no* procedures for the filing of claims and instead delegates to HCFA the authority to establish regulations. 42 U.S.C. § 1395n(a)(1). HCFA may establish both substantive regulations, which are entitled to the force and effect of law, and interpretive regulations, which are mere guidelines and not binding on any parties. 5 U.S.C. § 553; *Batterton v. Francis*, 432 U.S. 416, 425 n.9 (1976) *Schweiker,*

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13. (84a, 85a); *see also* fn. 9 and accompanying test, *supra.*

14. *See* page 14, *supra.*

supra, 450 U.S. at 789. HCFA must comply with the Administrative Procedure Act ("APA") requirements of public notice and comment before any substantive regulation may be validly promulgated. 5 U.S.C. § 553.[15] In addition to properly promulgated substantive regulations published in the C.F.R., HCFA has also produced numerous publications addressing a variety of administrative subjects. These include various manuals, such as the CM.

In examining the enforcement and application of regulations by administrative agencies, this Court has explained:

> The Administrative Procedure Act was adopted to provide, inter alia, that administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherent arbitrary nature of unpublished, ad hoc determinations.

Morton v. Ruiz, 415 U.S. 199, 232 (1974). In *Morton*, this Court held that the Bureau of Indian Affairs ("BIA") had improperly relied on a rule in the BIA Manual to deny a benefits claim. The court assumed that BIA could limit benefits to Indians living on reservations or in certain states, but noted "the question that remains is whether this has been validly accomplished". *Id.* at 231. Because the BIA failed to comply with the requirements of the APA, the court unanimously found the rule invalid. *Id.* at 235.

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15. HCFA's substantive regulations are published in the Code of Federal Regulations ("C.F.R."). See 42 C.F.R. § 400, et seq. The C.F.R. regulations never addressed where a claim form was to be filed or how it was to be completed. *See*, 42 C.F.R. § 405.250 (1987) (subsequently redesignated as 410.170(a) (1989); 42 C.F.R. § 405.1660 (1987) (subsequently redesignated and amended as 425.5(a)(5) (1989)).

It is well settled that the provisions of agency manuals, such as the CM, are merely interpretive regulations[16] which are not entitled to the force and effect of law and which have no binding effect. *Id.; Schweiker, supra,* 450 U.S. at 789; *St. Mary's Hospital v. Blue Cross and Blue Shield Assn,* 788 F.2d 888, 890 (2d Cir. 1986) (examining the Medicare Providers Reimbursement Manual); *Linoz v. Heckler,* 800 F.2d 871 (9th Cir. 1986) (concluding that because CM provisions were not promulgated under the APA, they could not be relied on by HCFA to deny a claim for benefits); *Glick, supra,* 714 F. Supp. at 41; *American Ambulance Service of PA v. Sullivan,* 716 F. Supp. 861, 871 (E.D. Pa. 1989) ("It is clear that the carriers manual and letter 10-80 [HCFA's letter to carriers] are interpretive rules. . ."). On this basis, both this Court and other federal courts have refused to compel a party to comply with such manual provisions. *See Schweiker, supra; Glick, supra.*

Glick is particularly relevant to the issues presented herein. In *Glick*, a Medicare carrier sought reimbursement from a physician for claims that the carrier had processed and paid. The carrier argued that Glick should repay those claims for which he failed to provide documentation required by the CM. Glick initiated suit to challenge the validity of the CM provisions and argued that because the CM was not promulgated under the mandates of the APA, it could not impose any filing requirements on him and could not be relied on to refuse to process and pay his claims. The *Glick* court agreed explaining: "to the extent that the regulations contained in the Carrier's Manual [CM] have not been officially promulgated, plaintiff [Glick] cannot be held accountable to them." 714 F. Supp. at 41.

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16. At one point, the Prosecution itself argued that the CM provisions were not rules or regulations. *See* fn. 19, *infra.*

Glick raised the same APA argument that Petitioners presented in this case: the CM can impose no obligation on the part of Medicare suppliers because it has never been promulgated in accordance with the mandates of the APA. When Petitioners initiated a suit for virtually the identical reasons as in *Glick*, however, Petitioners were indicted for fraud. It is indeed a travesty of justice to determine, as in *Glick*, that Medicare suppliers "cannot be held accountable" to CM provisions, yet in this case to find that Medicare suppliers are criminally liable for failure to comply with those provisions.

3. Failure To Comply With Interpretive Regulations Cannot Provide The Basis For A Conviction.

On appeal, the Second Circuit did not address the enforceability of the CM provisions, apparently assuming that they constituted valid substantive regulations, the violation of which could serve as the basis for a fraud conviction. The court stated that: "The Manual [CM] explains the basis upon which a provider of services is to determine to which carrier it should submit a claim" (8a), and that "it was the Manual that explained the proper address to be shown in box 31" (22a). On this basis, it affirmed the convictions, concluding that because the addresses Petitioners "gave in box 31. . .were not addresses from which the sale was made. . ." the Petitioners were guilty of providing "false information."[17] *Id.*

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17. Petitioners contend that contrary to the Second Circuit's assumption, the CM provisions were far from clear and did not explain at all what the provider of services *should* do in completing and submitting claims. *See* pp. 21-24, *infra*. In fact, it was box 24B of the claim form, not box 31 that asked for "Place of Service"and provided place of service codes (56a). It is undisputed that Petitioners always completed this box by filling in the code for "Patient's Home", that the patients' names and addresses were listed on the forms as requested, and that the parties were actually provided with the equipment.

Petitioners respectfully contend that it is precisely *because* the CM is the *only* document relied on by the Prosecution to establish that Petitioners provided "false information", that the conviction cannot stand.[18] The CM provisions are, at best, interpretive regulations, and in the rare criminal cases that have charged a failure to comply with interpretive regulations, the indictments and/or convictions have been overturned. *United States v. Vail,* 252 F. Supp. 823, 825 (S.D. Ohio, 1966) (dismissing Indictment for failure to file excise tax returns, because the filing regulations were never properly promulgated under the APA); *United States v. Zacher,* 586 F.2d 912, 914, 916-17 (2d Cir. 1978) (reversing bribery conviction because no Medicaid rule prohibited defendant's receipt of supplemental payments, even though he believed his actions were illegal or questionable); *United States v. Porter,* 591 F.2d 1048, 1057 (5th Cir. 1979) (reversing conviction because no statute or regulation prohibited doctors from submitting blood work to particular labs for the sole purpose of obtaining higher fees despite Medicare carrier publications and letters); *United States v. Reinis, supra,* 794 F.2d at 508. Petitioners simply may *not* be criminally punished for failure to comply with the CM provisions. Any other conclusion elevates the interpretive regulations of the CM to the level of substantive regulations and

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18. Nor did the Prosecution present any letter from any carrier that requested the branch office covering the point of sale be listed in box 31. Furthermore, an argument that carriers' letters would satisfy the publication requirements of the APA has previously been considered and rejected by the Federal Courts. The Fifth Circuit in *United States v. Porter, supra,* 591 F.2d at 1057, held that mere letters from Medicare carriers could not form the basis for a criminal prosecution. *Cf. Krieger v. Krauskopf,* 121 A.D.2d 448, 503 N.Y.S.2d 418 (2d Dept., 1986), *aff'd* 70 N.Y.2d 637, 518 N.Y.S.2d 957 (1987), *cert. denied,* 108 S.Ct. 731 (1988) (Letters from HCFA stating payment rules were of no force and effect absent a demonstration that the procedures of the APA for promulgation and publication of such rules had been followed). In this case, Petitioners could not have been expected to comply with the carriers' instructions, as the instructions were inconsistent and contradictory. *See* fn. 6 and accompanying text, *supra.*

vitiates the very purpose of the APA.

B. The Government's Position That The Carriers Manual Creates Enforceable Rules Is Impermissibly Inconsistent With Its Prior Position in Other Litigation And Violative Of Petitioners' Due Process Rights.

The Prosecution's position that the CM created enforceable "point of sale rules" is completely contradictory to the Government's prior position concerning the CM in *Melashenko v. Bowen*, No. CV-F-87-533, 5 C.C.H. Medicare/Medicaid, par. 38,827 (E.D. Cal. 1990).[19] Dr. Melashenko, excluded from participation in the Medicare program, sought a permanent injunction against the Office of Inspector General ("OIG") for its failure to follow CM procedures in refusing to reinstate him. The government successfully argued that the CM provisions "are not law or regulations", but merely "*guidelines which have no 'legal force' and are not binding on the Secretary.*" (116a). The Government explained that the CM provisions were never published in the Federal Register and were not promulgated in accordance with the APA. Accordingly, the government requested that if Court found the CM established "substantive rules, that it must strike them down as being violative of the APA". (118a).[20]

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19. Indeed, the Prosecution inconsistently characterized these CM provisions. At trial, it argued that the CM provisions created "point of sale rules" (61a-62a, 71a). On appeal, however, it argued that these CM provisions were not rules or regulations (106a-107a). The Prosecution made this latter assertion in response to Appellants' argument that before any CM provision can create a rule that places an obligation on Medicare suppliers, the CM provisions must comply with the mandates of the PRA. The Prosectuion argued that the CM is exempt from such PRA mandates because the CM provisions are merely explanatory guides (106a-107a).

20. This same argument was raised by Petitioners at trial (68a). Inexplicably, the trial judge rejected this argument without the benefit of an opinion stated from the bench or in a written decision.

The instant prosecution is based on CM provisions, which, as the Government argued in *Melashenko*, are of "no force and effect". The Government's inconsistent interpretation of the CM between the *Melashenko* case and the case at bar establishes a clear due process violation. *Cf. United States v. Bogart,* 783 F.2d 1428, 1438 (9th Cir. 1986) (remanding to determine whether Government's conduct was so "outrageous" as to constitute a due process violation, and observing that such conduct includes "those hopefully few cases where the crime is fabricated *entirely* by the police to secure the defendant's conviction. . ."). [21] The Government cannot in one case be permitted to argue that the CM provisions "have no legal force" and in another to argue that the CM provisions must be complied with under threat of criminal prosecution. *Cf. United States v. Goodwin,* 457 U.S. 368, 372 (1982) ("To punish a person because he has done what the law plainly allows him to do is a due process violation 'of the most basic sort' ").

C. The Carriers Manual Does Not Apply to Medicare Suppliers And Its Provisions Do Not Create The "Point Of Sale Rules" On Which The Convictions Were Based.

The Prosecution construed certain CM provisions to create the following "point of sale rules": CM provision 3102.b allegedly required Medicare suppliers to file claim forms with the carrier

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21. Throughout these proceedings, the Prosecution has continually read and relied on only selected portions of the CM provisions to create out of whole cloth these imaginary "point of sale rules". Finally, in summation, the prosecutor abandoned any attempt to even rely on the CM, as he created his own "point of sale rule." The Prosecution advised the jury that a supplier must have an office in the area of the "point of sale" (70a). The Record is completely devoid of *any* proof of this new point of sale rule. Indeed, the CM specifically contradicts this new rule; CM 3102.b (on which the prosecutor so heavily relies) gives an example of a carrier having processing jurisdiction in a location where the supplier does *not* have an office.(*see*, e.g., Example #3 at p. 136a).

located in the geographic location where the point of sale occurred, while CM provisions 4105.5 and 4011.8 allegedly required multi-office Medicare suppliers to place the address for the branch office covering the point of sale in box 31 of the claim form (37a-38a, 70a-71a). Petitioners argue, however, that even if the CM as a whole were treated as containing substantive regulations having the force and effect of law, those provisions do not creat the "point of sale rules" asserted by the Prosecution. Neither on its face nor through any reasonable interpretation can the CM as a whole, or any of its provisions, be construed to have imposed on Petitioners the requirements alleged by the Prosecution.

1. The Carriers Manual Applies To Carriers, Not Suppliers

Initially, it must be observed that the CM places *no* obligation on Medicare suppliers. *Glick, supra,* 714 F. Supp. at 41. The *Glick* court, in addition to finding that because "the regulations contained in the Carriers Manual [CM] have not been officially promulgated, plaintiff cannot be held accountable to them", *id.*, further observed that the CM "provisions are *designed to put carriers, not practitioners, on notice*". *Id.* (emphasis supplied).

The *Glick* rationale is completely supported by the publication, distribution, use and content of the CM. The CM is published by HCFA for Medicare carriers — it is, after all, titled *The Carriers Manual.* It is distributed by HCFA to carriers and it is *not* provided to Medicare suppliers.[22] It instructs the carriers and is used by them to decide how to process claims.[23]

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22. The Indictment mistakenly alleges that the CM "is provided to all Medicare suppliers." (37a). At trial, however, it was established that the CM is *not* provided to Medicare suppliers unless they specifically request it from HCFA and pay for it (62a-63a).

23. The Indictment itself admits this (37a-38a).

2. The Provisions Of The Carriers Manual Can Not Reasonably Be Construed To Create The "Point Of Sale Rules" Relied On By The Prosecution.

Even if, as the Prosecution argues, the CM could be held to impose obligations on Medicare suppliers, as well as carriers, the provisions relied on by the Prosecution cannot be construed to create the "point of sale rules." Indeed, the CM provisions explicitly contradict the Prosecution's arguement.[24] None of the CM provisions cited by the Prosecution, nor any other provision in the CM, ever refer to the term "point of sale."

The CM provisions relied on by the Prosecution speak of "jurisdiction for *processing* of claims", not filing of claims. CM 4105.5. Moreover, "the *carrier receiving* the claim must develop the location of sale", CM 4105.5, and "determine jurisdiction in referring the claim to the servicing carrier where appropriate", CM 4011.8, and finally, "if the request for Medicare payment

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24. CM provision 3102.b addresses carrier jurisdiction for payment requests and refers to CM provision 4105.8, which addresses carrier "jurisdiction for processing of claims." These provisions must be read in conjunction with CM provision 3110, which provides: "If the request for Medicare payment was misdirected, the *carrier* reroutes it." It is a basic principle of statutory interpretation that the statute must be construed wherever possible to give effect to all provisions and render apparently inconsistent provisions harmonious. *Northwest Hospital v. United States*, 4 Cl.Ct. 109, 112 (U.S.C.C.,1983); *United States v. Stauffer Chemical Co.*, 684 F.2d 1174, 1186 (6th Cir. 1982). Accordingly, the only permissible interpretation of these CM provisions is that they address a carrier's jurisdiction for *processing* claims, and they do not create a filing requirement on the part of Medicare suppliers.

CM 4105.5 never addresses box 31 of the claim form. The Prosecution tried to cure this obvious defect by arguing that the CCH Medicare/Medicaid Guide explains how to fill in box 31 (113a). The idea that an enforceable filing requirement could be created by a private publishing company is itself an absurdity and an obvious violation of Petitioners' due process rights.

was misdirected, the *carrier* reroutes it. . ." CM 3110. Particularly in the light of *Glick, supra,* these CM provisions suggest that a Medicare supplier may file his claim with any carrier, and the carrier, not the supplier, must determine the appropriate carrier for processing and reroute the claim.

It is a most basic tenet of statutory interpretation that the "plain meaning" of the words in the statute determine questions of interpretation. *Bethesda Hospital Assn. v. Bowen,* 485 U.S. 399, 403-04 (1988) (rejecting the Secretary's interpretation of the Medicare statute because "the strained interpretation offered by the Secretary is inconsistent with the express language of the statute"). Here, the Prosecution strains interpretation of the CM provisions by attempting to impose obligations on Medicare suppliers that are contradicted by explicit reference to carriers.

The claim form itself further refutes the Prosecution's argument concerning the alleged "point of sale rules". (56a). It does not state that a claim must be filed with any particular Medicare carrier. Moreover, box 31 of the claim form simply requests the supplier's name and address, it does not specify that multi-office suppliers list any particular branch office in box 31.[25]

Petitioners respectfully contend that because the CM places no obligation on Medicare suppliers and because it does not create the "rules" alleged by the Prosecution, the Second Circuit was plainly mistaken when it assumed that "the Manual [CM] explains the basis upon which a provider of services is to determine to which carrier it should submit a claim" (8a), and when it further stated "it was the manual that explained the proper address to be shown in box 31". (22a). Petitioners' failure to do that which

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25. Box 24 of the claim form does request "Place of Service" (56a). It is undisputed that Appellants listed the beneficiary's address on the claim form, and indicated in box 24 that the "place of service" was the beneficiary's address.

they were not required to do simply cannot constitute fraudulent conduct.

D. The "Point Of Sale Rules" Relied On By The Prosecution Are Unconstitutionally Vague.

Assuming, *arguendo*, that Medicare suppliers may be required to comply with CM provisions, *and* that the CM provisions relied on by the Prosecution do create "point of sale rules," those rules are unconstitutionally vague. In examining the validity of regulations or laws that are being used to criminally punish individuals, this Court has a:

> . . .long established practice of resolving questions concerning the ambit of a criminal statute in favor of leniency [citations omitted]. This practice reflects not merely a convenient maxim of statutory constructions. Rather, it is routed in fundamental principles of due process which mandate that no individual be forced to speculate, at peril of indictment, whether his conduct is prohibited [citations omitted]. Thus to insure that a legislature speaks with special clarity when marking the boundaries of criminal conduct, courts must decline to impose punishment for actions that are not 'plainly and unmistakably' proscribed [citations omitted].

Dunn v. United States, 442 U.S. 100, 112 (1979). In *Dunn,* the Supreme Court reversed a conviction on the grounds that the appellants' conduct was not clearly proscribed by the criminal statute.

Failure to comply with the "point of sale rules" could serve as the basis for an indictment only if the term "point of sale"

refers to a specific location, such that a supplier would clearly know to which carrier it must submit its claim forms, and which particular branch office it should list in box 31. The term "point of sale", however, has multiple definitions and is open to numerous interpretations.

The Indictment itself presents two different definitions for the term. At page 5 paragraph 14, it defines "point of sale" as "the location where the supplier meets with the beneficiary or receives the beneficiary's call for the supplier's services." At page 6 paragraph 15, the Indictment contradicts itself, defining "point of sale" as "the location where services were furnished" (37a-38a).[26]

The Prosecutor himself demonstrated confusion regarding his definition of "point of sale". At trial, he explained that "point of sale is the [patient's] home" (66a).[27] At other times during trial and in his appellate brief, however, he contradicted himself arguing that "point of sale" is determined by the office address of the supplier (73a, 97a). Petitioners question how, if the prosecution is unable to consistently define the term that is the

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26. In fact, a host of definitions or interpretations for the term "point of sale" are possible. Is "point of sale" — (1) where the beneficiary meets the supplier; or (2) where the beneficiary's call is received by the supplier; or (3) where the supplier shipped equipment from; or (4) where the equipment was shipped to; or (5) the beneficiary's address; or (6) the supplier's address? Obviously a situation could arise in which each of these incidents occurred in different states for a single claim. How is it then possible to determine the "point of sale"?

27. If the "point of sale" is the patient's home, the theory that Petitioners falsely completed box 31 to mislead carriers regarding the true point of sale is patently ridiculous. At the top of each claim form, clearly listed are boxes requesting the name and home address of the patient (*See* 56a, boxes 1 and 4). It was undisputed at trial that these boxes were always properly filled in.

essence of its fraud theory, Petitioners can be guilty of having committed fraud?

As the definition of "point of sale" is susceptible to more than one interpretation, any regulation that relies on this term to impose some obligation on the public cannot speak with clarity in marking the boundaries of criminal conduct. *See Dunn, supra,* 442 U.S. at 112; *United States v. Murphy,* 809 F.2d 1427, 1430-31 (9th Cir. 1987).

Murphy is closely analogous to the present case. In *Murphy*, the defendant was charged with conspiring to defraud the United States pursaunt to 18 U.S.C. § 371, by providing false information on a "currency transaction report". The Government argued that the language of the reporting form required the defendant to disclose the person from whom he obtained the currency, and that by instead listing the person for whom the currency was being deposited, Murphy had made false statements and committed fraud.

The indictment was dismissed for failure to state facts sufficient to constitute an offense against the United States. The Ninth Circuit affirmed, finding the currency transaction reporting form ambiguous and that it did not clearly request the information the indictment charged should have been listed. The form was open to more than one interpretation and the defendant was not required to look to the "statutory language to clarify his duties" as to completing it. The Court stated:

> Due process requires that penal statutes define criminal offenses with sufficient clarity that an ordinary person can understand what conduct is prohibited. . . Section 5313 and its regulations do not clearly require depositors to identify the source of their funds. Therefore, the imposition of

> criminal sanctions on these facts would violate due process.

809 F.2d at 1431 (citations omitted).

In the instant case, as in *Murphy*, the Indictment charges that the Petitioners withheld information that they were allegedly obligated to give, and in each case the form seeking this information is unclear and ambiguous. The reasoning and holding of *Murphy* therefore should be applied to the instant action.

II.

THE PUBLIC PROTECTION CLAUSE OF THE PAPERWORK REDUCTION ACT PROHIBITS THIS CRIMINAL PROSECUTION.

In enacting the Paperwork Reduction Act ("PRA"), Congress required all federal agencies, particularly HCFA[28], to comply with specific regulations before any request for information can be made from the public. 44 U.S.C. § 3507. *Dole v. United Steel*

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28. The Senate report concerning the enactment of this legislation made the following observations under its heading of "Need for Legislation":

> Federal paperwork requirements, whether they are. . ., medicare forms. . .are something each individual touches, feels and works on. The cumulative impact is excessive. . . .
>
> The burden of filling out forms is causing doctors to discourage medicare business. Processing a medicare claim has become a nightmare for many older Americans. Hospitals have witnessed an explosion in paperwork since the advent of medicare. One hospital President in St. Louis testified that his institution's clerical staff increased fifteen percent in the first year of medicare. . . .

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Workers of America, 58 L.W. 4200, 4202 (1990); *Kuzma v. United States Postal Service,* 798 F.2d 29, 31-32 (2d Cir. 1986), *cert. denied,* 479 U.S. 1043 (1987). The PRA prohibits a federal agency from adopting regulations that impose collection requests on the public without first receiving approval from the Office of Management and Budget ("OMB") and obtaining an OMB control number, which must appear on the face of the information collection request. 44 U.S.C. § 3507; *Dole, supra; Kuzma, supra.* The PRA further contains a Public Protection Clause that prohibits any penalty from being imposed upon the public for failure to comply with a request that has not received OMB approval or does not display a valid OMB control number.[29]

This Court has recently reviewed the PRA's Public Protection Clause[30] and held:

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> Most frightening was the testimony of several witnesses who said that they were 'afraid of their government'. They had been bombarded with Government forms, neglected or wrongly answered some particular form, and were afraid that the 'Government' was going to 'get' them as a result — a nagging feeling of fear. . . .
>
> The Act establishes a framework of accountability and a reasonable set of controls to make the shower of paperwork requirements that rain upon the public more manageable.
>
> 5 U.S. Code, Cong. & Ad. News (1980), PL 96-930, Senate Report Number 96-930, pp. 6243-44.

29. The full text of this section of the PRA is recited in the Appendix.

30. The Court's review of the PRA concerned a different issue:

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> If a request does not receive OMB approval, it is not issued a control number, and the agency is prohibited from collecting the information.... In addition, if the agency nevertheless promulgates the paperwork requirement, members of the public may ignore it without risk of penalty.

Dole v. United Steel Workers of America, 58 L.W. 4200, 4202 (Feb. 2, 1990) (citations omitted).

In the present case, the Second Circuit asssumed that the CM provisions constituted an information collection request which required OMB approval.[31] (21a). Nevertheless, the Second Circuit concluded that the Public Protection Clause of the PRA was not applicable because the "gravamen of the crimes for which the appellants were convicted... was not 'failing to... provide information' but knowingly providing false information" (21a). The Second Circuit viewed the Petitionerrs' failure to list a particular branch office address in box 31 of the claim form as a "deliberate misstatement": "The addresses they gave in box 31... were not the addresses from which the sale was made...", finding that "it was the Manual [CM] that explained the proper

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whether the OMB has the authority to review agency regulations concerning the disclosure of information to parties other than government agencies. The court concluded that the PRA grants OMB the authority to review only information collection requests designed "to provide information to a federal agency". 58 L.W. at 4203. Because Medicare carriers contract with HCFA and collect information on its behalf, the CM provisions are intended to provide information to a federal agency. 42 C.F.R. § 421.200 (1989). This Court acknowledged that "typical information collection requests include. . .Medicare forms. . ." 58 L.W. at 4202. Accordingly, the information collection requests of the CM are clearly within the jurisdiction of OMB.

31. Neither the CM provisions relied on by the Prosecution, nor the CM as a whole, ever received OMB approval or listed a valid OMB control number.

address to be shown in box 31, i.e. point of sale" (22a)[32]. Accordingly, the Second Circuit concluded that the information given by Petitioners was false because it was not the information requested in the CM.

It is respectfully submitted that the Second Circuit is plainly mistaken. Petitioners contend that precisely *because* it is the CM, and not the claim form, that defines the "proper address" to be shown in box 31[33], and *because* the CM provisions never received OMB approval, Petitioners were entitled to ignore the CM's information collection requests in completing the claim form without risking criminal prosecution. 5 C.F.R. § 1320.5(a); *see United States v. Hatch,* 919 F.2d 1394, 1397-98 (9th Cir. 1990) (reversing conviction because C.F.R. regulation had not received OMB approval); *United States v. Smith,* 866 F.2d 1092, 1098-99 (9th Cir. 1989) (reversing conviction because filing regulations never received OMB approval); see *Dole, supra,* 58 L.W. at 4202. Moreover, if Petitioners were entitled to ignor the CM provisions altogether when completing the claim forms, their failure to list the addresses that are requested by the CM cannot constitute fraud.

The analysis of the Second Circuit would vitiate the purpose of the PRA and is inconsistent with its legislative history. The Public Protection Clause was intended to apply particularly in cases like this, in which the Government alleges that a "wrongly

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32. Petitioners respectfully contend, contrary to the Second Circuit's finding, that the CM provisions were far from clear and they did not fully explain that a particular branch office must be listed in box 31. In fact, the CM provisions never referred to this box on the claim form. *See* fn. 24 and accompanying text.

33. It is undisputed that the claim form does not require that any particular branch office be listed in box 31. (56a). The Second Circuit even quoted the claim form's language: "Box 31 of the form asks for the 'PHYSICIAN'S OR SUPPLIER'S NAME ADDRESS ZIP CODE' and 'TELEPHONE NUMBER' " (11a).

answered... form" is sufficient basis for a charge of fraud.[34]

The Second Circuit's analysis additionally refuses to credit the determination by the OMB regarding this information collection request. The OMB specifically considered the CM provisions' reporting requirements regarding a listing of a particular branch office on the claim form. The OMB advised HCFA that no such reporting requirement had receivede OMB approval, and as such, the Public Protection Clause of the PRA applied (87a-88a). The OMB specifically explained: "I would like to make you aware that, if a contractor [carrier] imposes a requirement for information from the public that is not required on the HCFA-1500 [claim form] or other approved collections subject to the PRA, the public protection clause of the Act (section 3512) applies." (88a). The OMB has further explained that: "While the form 1500 [claim form] has been approved, the requirement in the manual [CM] is not on the form, nor is the requirement directed to respondents, made readily available to the respondents, or identified as instructions to the respondents."(91a).

The PRA authorized the OMB to make such determinations. 44 U.S.C. § § 3503, 3518; *Dole, supra,* 58 L.W. at 4202. As OMB's determination was not unreasonable, the courts may not substitute their opinion for that of the agency. *N.L.R.B. v. Curtin, Matheson Scientific, Inc.* 110 S.Ct. 1542, 1549 (1990). Further, because the claim form did receive OMB approval, the public is entitled to rely solely on that form to contain all information collection requests and reporting requirements. The public cannot be expected or required to be aware of or comply with any requirements stated in the CM, as the CM was not OMB approved.

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34. *See* fn. 28, *supra.*

III.

THE MAGISTRATE HAD NO STATUTORY JURISDICTION TO SELECT A JURY IN THIS FELONY CASE WITHOUT PETITIONERS' KNOWING WRITTEN WAIVER.

The jury selection in this case was conducted on April 3, 1989 before Magistrate David F. Jordan. The relevant case law in the Second Circuit at that time provided that a Magistrate had the authority to select a jury in a criminal case, even over the explicit objectgion of the defendant. *United States v. Garcia,* 848 F.2d 1324, 1327-29 (2d Cir. 1988). Accordingly, any objection by Petitioners on this issue was futile. *United States v. France,* 886 F.2d 223, 227-28 (9th Cir. 1989). Moreover, there could be no knowing waiver of this right, as it had not yet been clearly articulated by this Court.

On Appeal, Petitioners relied on this Court's decision in *United States v. Gomez,* 109 S.Ct. 2237 (1989), *rev'ing. United States v. Garcia, supra.* The *Gomez* decision explained that the Magistrate's statutory jurisdiction to preside in a criminal case "depends on defendant's specific, written consent". 109 S.Ct. at 2245. Because the Petitioners never specifically consented in writing to the selection of the jury by a Magistrate, the Magistrate was without jurisdiction and a re-trial is required.

The Second Circuit rejected this argument on the ground that: "A defendant must 'object to the selection of the jury by a magistrate' " (33a, citing *United States v. Wong,* 884 F.2d 1530, 1538-39 (2d Cir. 1989)). There is presently a conflict between the circuits on this issue. The Ninth Circuit has held that because a Magistrate's jurisdiction to select a jury is contingent upon a defendant's written consent, the failure to object does not constitute a waiver of the defendant's constitutional right to have

an Article III Judge preside at this critical stage of the criminal proceedings. *United States v. Aikins,* 912 F.2d 285, 288 (9th Cir., 1990) (ordering re-trial of a felony case where the defendants had actually orally consented to the selection of a jury by a Magistrate, but "their consent was not in writing").

The Supreme Court recently considered this issue and affirmed the Ninth Circuit's reversal of a conviction on these grounds. *United States v. France,* 886 F.2d 223 (9th Cir. 1989), *aff'd by an equally divided Court,* 59 L.W. 4089 (Jan. 22, 1991) (per curiam) (Justice Souter did not participate in this decision). This Court further has granted certiorari in another Second Circuit case that presents the identical issue. *Peretz v. United States.,* 59 L.W. 3501 (Jan. 22, 1991).

This Petition for certiorari should be granted in order to resolve the conflict between the Second and Ninth Circuits on the issue as to whether a Magistrate has the jurisdiction to select a jury in a criminal case in the absence of a specific written and knowing waiver of defendant. At the least, this petition should be held pending this Court's decision in *Peretz.*

CONCLUSION

For the reasons stated above, the Petition for writ of certiorari should be granted and the Judgment of the Court of Appeals summarily reversed under the requirements of the APA, the PRA and *Gomez v. United States.* Alternatively, the matter should be set down for full briefing and oral argument. At the least, the Petition should be held pending the decision in *Peretz.*

Respectfully submitted,

Dated: New York, New York
February 6, 1991

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